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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER
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ART UNIT	PAPER NUMBER
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Office Action Summary**

Application No.

09/552,147

Applicant(s)

KOROL ET AL.

Examiner

Anne Kubelik

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1638

2. Applicant's election with traverse of group I (claims 1-22) in Paper No. 7 is acknowledged. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, and because Applicant cancelled claims 23-30, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

*Oath/Declaration*

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The date of signing by the first applicant is not present.

It does not identify the post office address of each inventor. A post office address is an address at which an inventor customarily receives his or her mail and may be either a home or business address.

It appears that at least one full given name of applicants T. Fahima and E. Nevo is not present either in the signature or elsewhere in the papers. This application will not be passed to issue until the omitted names have been supplied or unless a statement has been supplied over

the applicants' signatures setting forth that the names as signed are the actual full name of the applicants. See MPEP § 605.04.

### *Specification*

4. The abstract of the disclosure is objected to because it is single spaced and has typographical errors. Correction is required. See MPEP § 608.01(b).
5. A substitute specification including the claims is required pursuant to 37 CFR 1.125(a) for the following reasons:

The --What is claimed is-- statement on pg 26 is written as "We is claimed is".

Correction is required.

The flow chart on pg 14 of the specification should be deleted and submitted as a Figure

There are inadequate upper margins, resulting in hole punches that obliterate the text.

Punctuation is missing throughout the text. For example, on pg 21, line 5, there should be a period between 'obtained' and "Southern". See also pg 20, lines 19 and 23.

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

***Claim Objections***

6. Claims 1, 5, 16, 19 and 22 are objected to because of the following informalities:

In claim 1(e) "pollens" should be --pollen--.

In claim 5, there should be an --a-- before "5%".

In claim 16 --acetyltransferase-- is misspelled "acetyltransferase". Also there should be an --a-- before "phosphinothricin".

Claim 19 recites "monocots **is**" (error in bold for emphasis)

Claim 22 recites "gymnosperms **is**" (error in bold for emphasis).

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-18 and 20-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a silicon carbide/pollen-mediated method of transformation of maize, does not reasonably provide enablement for use of that method in all sexually-reproducing plants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to a method for genetic transformation of any plant species with sexual reproduction, including the physiologically and taxonomically divergent

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gymnosperms and angiosperms, by transforming pollen using silicon carbide whiskers. Gymnosperms encompass a multitude of divergent plant species such as ginkgo and pine. Dicots encompass a multitude of divergent species, such as cotton, tobacco, tomato, cucumber, soybean, sunflower, and oak. Even monocots encompass divergent species, such as maize, onion, lily, palm, and orchid. The instant specification, however, only provides guidance for use of this method in maize.

Pollen mediated transformation of plants other than maize is unpredictable. van der Leede-Plegt (1995, Transgen. Res. 4:77-86) teach that pollen-mediated transformation of *Nicotiana glutinosa* resulted in chromosomal deletion (pg 85, right column). Burke et al (1999, US Patent 5,929,300) teach the hazards of exposure of "dry stigma" pollen, like that from cotton, to moisture (column 2, lines 1-28). As the instant specification does not present working examples of pollen-mediated transformation in plant species other than maize, and given the structural and biochemical differences in pollen grains produced by gymnosperms, dicots and non-maize monocots, the unpredictable behavior of pollen-mediated transformation has not been overcome.

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate methods for genetic transformation of any plant species, including physiologically divergent monocots, dicots and gymnosperms, with sexual reproduction by transforming pollen using silicon carbide whiskers.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention.

Dependent claims are included in all rejections.

Claims 1-11 and 17 are indefinite for their recitation of "method for genetic transformation of any plant species with sexual reproduction based on a pollination-fecundation process". It is unclear if the phrase "based on a pollination-fecundation process" is intended to modify "sexual reproduction" or "method" or "species". In claims 2-11 and 17, note that for clarity, and to reduce confusion regarding phrase modification, "A method for genetic transformation of any plant species with sexual reproduction based on the pollination-fecundation process of claim 1" can be replaced with --The method of claim 1--.

Claim 17 is not written in proper Markush format. The claims should be in the format "selected from the group consisting of A, B, C and D." It is suggested that "in any plant species with sexual reproduction comprising" be replaced with --wherein the plants are selected from the group consisting of--. Note that this would also require that "species" be deleted from "method for genetic transformation of any plant species" in claims 1-11 and 17. If "species" is left in claim 17, then the group must list actual plant species. See MPEP 2173.05(h).

Claims 18 and 20 are not written in proper Markush format. The claims have only one member of the group. See MPEP 2173.05(h).

Claims 3 is indefinite for its recitation of "preferred", because it is unclear whether the limitation(s) following the word are part of the claimed invention. See MPEP § 2173.05(d).

Claim 7 recites the limitation "said preferred pollen germination medium" in line 3. There is insufficient antecedent basis for this limitation in the claim. Also it is unclear whether the limitations following the word "preferred" are part of the claimed invention.

Claims 2-3 recite the limitation "said silicon carbide fibers" in line 3. There is insufficient antecedent basis for this limitation in the claim.

In claim 1, part (g), it is unclear to what the paste is being applied.

Claim 9 is indefinite for its recitation of the abbreviation "TE".

In claim 4 it is unclear where in the process of claim 1 the aqueous solution for silicon carbide fibers is used.

Claim 5 recites the limitation "said solution" in line 5. There is insufficient antecedent basis for this limitation in the claim. It is also unclear which solution is being referred to.

In claim 10, it is unclear when in the process that the DNA solution is further incubated, as 1) it was not incubated a first time and 2) claim 10 does not indicate between which steps of claim 1 the incubation occurs.

In claim 11 --transformant-- is misspelled "transformate" in line 3.

Claim 11 is indefinite in its recitation of "performed by specific cloned selectable markers". First, in reference to selection of transformants, selectable marker genes are used. Second, it is unclear how selectable markers themselves perform selection; generally, a person uses selectable marker genes to perform selection. When "markers" is replaced with "marker genes", claims 12-16 will also have to be amended.



Claims 11 and 13 are indefinite in their recitation of "some drugs". It is unclear what Applicant intends by this phrase. It is unclear if the phrase means the resistance is to certain drugs but not others or if the resistance is to an indefinite quantity of drugs.

It is unclear in claim 11 how "providing resistance to some drugs" differs from "having phenotypic expression", as resistance to an antibiotic, for example, is a phenotypic trait. Additionally, the claim should be written in Markush format. See MPEP 2173.05(h).

Claims 12 is indefinite in its recitation of "selectable marker ... is an anthocyanin regulator". A selectable marker may be a gene regulating anthocyanin levels or anthocyanin biosynthesis, but anthocyanin regulators are not themselves selectable markers.

Claims 13 is indefinite in its recitation of "selectable markers ... are antibiotics or herbicides". A selectable marker may be a gene providing resistance to an antibiotic or a herbicide, but antibiotics and herbicides are selection agents rather than selectable markers. Additionally, herbicides are not conventionally thought of as drugs.

Claims 11 and 13-15 are indefinite in their recitation of "markers providing resistance to antibiotics". It is unclear if resistance to all antibiotics is intended. Similarly, claim 16 is indefinite for its recitation of "markers providing resistance to herbicides": it is not clear if resistance to all herbicides is intended.

Claims 14-15 recites the limitation "said selectable markers providing resistance to antibiotics" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 16 recites the limitation "said selectable markers providing resistance to herbicides" in line 2. There is insufficient antecedent basis for this limitation in the claim.

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Claim 15 recites "markers ... is kanamycin gene". It should be a "kanamycin resistance gene". Note also that an "a" is missing before "kanamycin" and that there is a plurals agreement error.

Claim 14 recites "markers ... is neomycin phosphotransferase gene". An "a" is missing before "neomycin", and there is also a plurals agreement error.

It is unclear in claim 21 if both melon and tomato are intended to be transformed at the same time. If either are intended, replace "and" with --or--

### ***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1-19 rejected under 35 U.S.C. 103(a) as being unpatentable over Dupuis et al (1993, Plant Cell Rep. 12:607-611) in view of each of Kaeppler et al (1992, Theor. Appl. Genet. 84:560-566) and Frame et al (1994, Plant J. 6:941-948).

The claims are drawn to method for genetic transformation of any plant species with sexual reproduction by transforming pollen using silicon carbide whiskers. Dependent claims limit the method to silicon fibers of a certain size and to certain genes.

Dupuis et al disclose transformation of male reproductive tissues via particle bombardment with anthocyanin marker genes and with the  $\beta$ -glucuronidase gene (pg 608, right

column, paragraph 2, to pg 610, left column, paragraph 3). Dupuis et al do not disclose transformation using silicon carbide fibers.

Kaeppler et al teach transformation of maize and tobacco cells using silicon carbide fibers (pg 561, right column, to pg 562, left column). Kaeppler et al teach transformation with the *bar* and *npIII* genes (paragraph spanning the columns, pg 561).

Frame et al teach transformation of maize with the *bar* gene using silicon carbide fibers and subsequent regeneration into plants (pg 943, left column, paragraph 2, to pg 945, right column, paragraph 1).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to male reproductive tissues using one physical transformation method, particle bombardment, as taught by Dupuis et al, and to modify that to use another physical transformation method, silicon carbide fibers, as described in Kaeppler et al and Frame et al. One of ordinary skill in the art would have been motivated to do so because of the suggestion of Kaeppler et al to transform walled cells and to use the relatively inexpensive silicon carbide procedure in place of more expensive procedures like particle bombardment (pg 561, left column, paragraph 1, and pg 565, right column, paragraph 2)

13. Claims 20-22 are free of the prior art, given the failure of the prior art to teach pollen mediated transformation of dicots using silicon carbide fibers and given the inherent unpredictability of pollen mediated transformation of dicots or gymnosperms.

*Conclusion*

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059.

The examiner can normally be reached on Monday through Friday, 8:15 am - 4:45 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Anne R. Kubelik, Ph.D.  
August 2, 2001

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180-16-38

